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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SUPERNUS PHARMACEUTICALS, INC., **Plaintiff,** **v.** **APOTEX INC. and APOTEX CORP.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff Supernus Pharmaceuticals, Inc. ("Supernus" or "Plaintiff"), by its undersigned attorneys, for its Complaint against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 7,722,898 ("the '898 patent"), United States Patent No. 7,910,131 ("the '131 patent"), United States Patent No. 8,617,600 ("the '600 patent"), United States Patent No. 8,821,930 ("the '930 patent"), United States Patent No. 9,119,791 ("the '791 patent"), United States Patent No. 9,351,975 ("the '975

patent"), United States Patent No. 9,370,525 ("the '525 patent), United States Patent No. 9,855,278 ("the '278 patent"), and United States Patent No. 10,220,042 ("the '042 patent"), attached hereto as Exhibits A–I (collectively, "the patents in suit").

THE PARTIES

2. Plaintiff Supernus is a corporation organized and existing under the laws of Delaware, having its principal place of business at 9715 Key West Avenue, Rockville, Maryland 20850.

3. Upon information and belief, Apotex Corp. is a corporation organized under the laws of Delaware and operating at its principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

4. Upon information and belief, Apotex Corp. is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and directly and/or indirectly selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

5. Upon information and belief, Apotex Corp., either directly or through one or more of its affiliates and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic pharmaceutical products, including in the State of New Jersey.

6. Upon information and belief, Apotex Corp. is registered as a wholesale drug distributor in the State of New Jersey under Registration No. 5003192.

7. Upon information and belief, Apotex Inc. is an entity organized under the laws of Canada having a place of business at 150 Signet Drive, Toronto, ON M9L 1T9, Canada. Upon information and belief, Apotex Inc. is wholly-owned by defendant Apotex Corp. Upon

information and belief, Apotex Inc. acts at the direction of, under the control of, and for the direct benefit of Apotex Corp. and is controlled and/or dominated by Apotex Corp.

8. Upon information and belief, Apotex Inc. is in the business of, *inter alia*, developing, manufacturing, marketing, distributing, and/or selling generic pharmaceutical products throughout the United States (including in the State of New Jersey), and importing generic pharmaceutical products into the United States (including into the State of New Jersey).

9. Upon information and belief, Apotex Corp. and Apotex Inc. filed Abbreviated New Drug Application ("ANDA") No. 213369 ("the Apotex ANDA") with the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of generic oxcarbazepine extended-release tablets, containing 150 mg, 300 mg, and 600 mg of oxcarbazepine ("the Apotex Product").

JURISDICTION AND VENUE

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has personal jurisdiction over Defendants under: (i) Fed. R. Civ. P. 4(k)(1) and N.J. Ct. R. 4:4-4; and/or (ii) Fed. R. Civ. P. 4(k)(2).

12. Upon information and belief, Defendants have purposefully availed themselves of the privilege of doing business in the State of New Jersey by continuously and systematically placing goods in the stream of commerce for distribution and sale throughout the United States, including the State of New Jersey. For example, upon information and belief, Defendants state on their website that they "export to more than 115 countries and territories, and operate in more than 45 countries, including a significant presence in the US, Mexico and India where we continue to invest." Apotex Website, https://www1.apotex.com/us/about-us/about-apotex (last visited June 25, 2020). Upon information and belief, Defendants maintain a broad

distributorship network within the State of New Jersey and enjoy substantial income from sales of its generic pharmaceutical products in this State.

13. On information and belief, Apotex Corp. is a subsidiary of Apotex Inc. and is controlled and dominated by Apotex Inc. On information and belief, Apotex Inc. and Apotex Corp. operate as part of a single, integrated generic pharmaceutical manufacturer with Apotex Inc. as the ultimate parent. Apotex's website states that Apotex is a "global pharmaceutical company that produces high-quality, affordable medicines (both generic and innovative pharmaceuticals) for patients around the world," that it "employ[s] more than 8,000 people worldwide in manufacturing, R&D and commercial operations," and "[t]hrough vertical integration, Apotex is comprised of multiple divisions and affiliates," including "Apotex Inc., focused on generics." Apotex Website, https://www1.apotex.com/global/about-us/about-apotex (last visited June 25, 2020).

14. Upon information and belief, Apotex Corp. is registered as a wholesale drug distributor in the State of New Jersey under the Registration No. 5003192. Apotex Corp. has, therefore, purposefully availed itself of the rights, benefits, and privileges of New Jersey's laws.

15. On information and belief, Apotex Corp. and Apotex Inc. have been, and continue to be, joint and prime actors in the drafting, submission, approval, and maintenance of the Apotex ANDA.

16. This Court has personal jurisdiction over Defendants because, *inter alia*: (i) Apotex Inc., together with Apotex Corp., has committed, induced, or contributed to acts of patent infringement in New Jersey; (ii) Defendants are doing business in New Jersey and maintain continuous and systematic contacts with this Judicial District; (iii) Defendants directly or indirectly through agents regularly do or solicit business in New Jersey and/or derive

substantial revenue from services or things used or consumed in New Jersey; (iv) Defendants transact business, perform work, and contract to supply services or products in New Jersey; (v) Defendants have availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in multiple New Jersey actions (*see infra* paragraph 18); and (vi) Apotex Corp. is registered as a wholesale drug distributor in the State of New Jersey under Registration No. 5003192.

17. Apotex Corp. and Apotex Inc.'s tortious acts of (i) preparing and filing ANDA No. 213369 with a paragraph IV certification to the patents in suit for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the patents in suit; and (ii) directing notice of its ANDA submission to Plaintiff Supernus, are acts with real and injurious consequences giving rise to this infringement action, including the present and/or anticipated commercial manufacture, use, and/or sale of Apotex's ANDA Product before the expiration of the patents in suit throughout the United States, including in this Judicial District. Because defending against an infringement lawsuit such as this one is an inherent and expected part of a generic ANDA filer's business, Apotex Corp. and Apotex Inc. should reasonably anticipate being sued in New Jersey.

18. This Court also has personal jurisdiction over Apotex Inc. and Apotex Corp. because Apotex Inc. and Apotex Corp. have previously submitted to the jurisdiction of this Court and have previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g., Apotex Inc., et al. v. Pharmaceutical Resources, Inc., et al.*, Civil Action No. 06-01153 (JLL)(MF) (D.N.J.) (Apotex Corp. and Apotex Inc. filed a complaint for a

declaratory judgement of no patent infringement); *Patheon Softgels Inc., et al. v. Apotex Inc., et al.*, Civil Action No. 17-13819 (MAS)(LHG) (D.N.J.) (Apotex Corp. and Apotex Inc. did not contest jurisdiction); *Dexcel Pharma Technologies Ltd., et al. v. Apotex Corp., et al.*, Civil Action No. 17-02423 (SDW)(LDW) (D.N.J.) (same); *Boehringer Ingelheim Pharmaceuticals, Inc., et al. v. Apotex Inc., et al.*, Civil Action No. 18-11350 (MAS)(LHG) (D.N.J.) (Apotex Corp. and Apotex Inc. filed a counterclaim and did not contest jurisdiction); *Mitsubishi Tanabe Pharma Corp., et al. v. Apotex Inc., et al.*, Civil Action No. 17-05278 (RMB)(JS) (D.N.J.) (same); *AstraZeneca AB, et al. v. Apotex Corp., et al.*, Civil Action No. 15-08492 (FLW)(DEA) (D.N.J.) (same); *Apotex Inc. v. Shire LLC*, Civil Action No. 08-03598 (SRC)(MAS) (D.N.J.).

19. In the alternative, this Court has jurisdiction over Apotex Inc. because the requirements of Fed. R. Civ. P. 4(k)(2)(A) are met as (a) Supernus's claims arise under federal law; (b) Apotex Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Apotex Inc. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

20. Upon information and belief, if ANDA No. 213369 is approved, Apotex's ANDA Product will be marketed and distributed by Defendants in the State of New Jersey, prescribed by physicians practicing in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and 1391(c), and § 1400(b).

22. Venue is proper for Apotex Inc. under 28 U.S.C. §§ 1391 and/or 1400(b), because, *inter alia*, Apotex Inc. is subject to personal jurisdiction in this Judicial District, as set forth above, has committed an act of infringement and will commit further acts of infringement in this Judicial District, as set forth above, and/or continuously transacts business in this Judicial District, as set forth above.

23. Venue is proper for Apotex Corp. under 28 U.S.C. §§ 1391 and/or 1400(b). As set forth above, Apotex Corp. has committed and will commit further acts of infringement in this Judicial District. In addition, Apotex Corp. does business in this Judicial District through a permanent and continuous presence in the State of New Jersey. For example, Apotex Corp. is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003192 and continuously sells its products in this Judicial District. Upon information and belief, Apotex Corp. employs a salesforce that includes personnel that regularly and continuously work in this Judicial District and, if Apotex Corp. succeeds in obtaining FDA approval, Apotex Corp. will use its salesforce to sell the Apotex ANDA Product in the State of New Jersey.

FACTS AS TO ALL COUNTS

24. Supernus owns New Drug Application ("NDA") No. 202810, which was approved by the FDA for the manufacture and sale of oxcarbazepine extended-release tablets, 150 mg, 300 mg, and 600 mg, which Supernus markets under the name Oxtellar XR®.

25. Oxtellar XR® is an antiepileptic drug indicated for: (i) adjunctive therapy in the treatment of partial seizures in adults; and (ii) adjunctive therapy in the treatment of partial seizures in children 6 to 17 years of age.

26. The '898 patent, entitled, "Modified-Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent

and Trademark Office on May 25, 2010, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '898 patent.

27. The '131 patent, entitled, "Method of Treating Seizures Using Modified Release Formulations of Oxcarbazepine" was duly and legally issued by the United States Patent and Trademark Office on March 22, 2011, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '131 patent.

28. The '600 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on December 31, 2013, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '600 patent.

29. The '930 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on September 2, 2014, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '930 patent.

30. The '791 patent, entitled, "Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof" was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the '791 patent.

31. The ’975 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on May 31, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’975 patent.

32. The ’525 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on June 21, 2016, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’525 patent.

33. The ’278 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on January 2, 2018, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’278 patent.

34. The ’042 patent, entitled, “Modified Release Preparations Containing Oxcarbazepine and Derivatives Thereof” was duly and legally issued by the United States Patent and Trademark Office on March 5, 2019, to Supernus upon assignment from inventors Padmanabh P. Bhatt, Argaw Kidane, and Kevin Edwards. Supernus owns all rights, title, and interest in the ’042 patent.

35. Pursuant to 21 U.S.C. § 355(b)(1), the patents in suit are listed in FDA’s publication titled, “Approved Drug Products with Therapeutic Equivalence Evaluations”

(commonly known as the "Orange Book") in connection with Oxtellar XR®. Supernus submitted the patents in suit to FDA to be listed in the Orange Book for NDA No. 202810.

36. Upon information and belief, Defendants worked in concert to prepare, submit, and file the Apotex ANDA with the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product and included a "paragraph IV" certification seeking approval before the expiration of patents in suit.

37. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such a letter include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)-(ii).

38. On or about May 13, 2020, Apotex sent a letter purportedly pursuant to § 505(j)(2)(B)(iv) of the FDCA and 21 C.F.R. §§ 314.94, 314.95 regarding the Apotex Product and the '898 patent, the '131 patent, the '600 patent, the '930 patent, the '791 patent, the '975 patent, the '525 patent, the '278 patent, and the '042 patent (the "May 13 Notice Letter").

39. The May 13 Notice Letter contends that the Apotex Product does not infringe independent claim 1 of each of the patents in suit. The May 13 Notice Letter does not include

any non-infringement contentions unique to claims 2-20 of the ’898 patent, claims 2–24 of the ’131 patent, claims 2–22 of the ’600 patent, claims 2-20 of the ’930 patent, claims 2-24 of the ’791 patent, claims 2-20 of the ’975 patent, claims 2-21 of the ’525 patent, claims 2-21 of the ’278 patent, and claims 2-27 of the ’042 patent.

40. The May 13 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants’ opinion that the patents in suit are unenforceable.

41. The May 13 Notice Letter does not include any detailed statement of the factual and legal basis for Defendants’ opinion that the patents in suit are invalid beyond a vague and unsupported contention that the patents in suit are invalid as “indefinite” and “for lacking enablement and written description.”

42. The May 13 Notice Letter does not contend that the patents in suit are invalid as anticipated or obvious. In fact, the May 13 Notice Letter does not include any prior-art based invalidity contentions based on 35 U.S.C. § 102 or 35 U.S.C. § 103.

43. The May 13 Notice Letter does not include any description of the composition, formulation, ingredients, development, manufacture, or testing of the Apotex Product beyond a vague and unsupported statement that the Apotex Product “does not have any of the excipients recited” in certain claims of the patents in suit. Plaintiff and Defendants did not reach agreement on mutually acceptable terms for an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). As of the filing of this Complaint, Defendants have not produced the Apotex ANDA to Plaintiff.

FIRST COUNT
(Defendants’ Infringement of the ’898 Patent)

44. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

45. Upon information and belief, Defendants seek FDA approval for the manufacture, use, marketing, sale, and/or distribution of the Apotex Product.

46. Upon information and belief, Defendants included a paragraph IV certification to the ’898 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the ’898 patent.

47. Upon information and belief, Defendants will commercially manufacture, use, sell, offer for sale, and/or import the Apotex Product upon, or in anticipation of, FDA approval.

48. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the ’898 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the ’898 patent is an act of infringement by Defendants of one or more claims of the ’898 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

49. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly and/or indirectly, one or more claims of the ’898 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

50. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’898 patent under 35 U.S.C. § 271.

51. Defendants’ infringement of the ’898 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’898 patent.

52. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’898 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the ’898 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

SECOND COUNT
(Defendants’ Infringement of the ’131 Patent)

53. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

54. Upon information and belief, Defendants included a paragraph IV certification to the ’131 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the ’131 patent.

55. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the ’131 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the ’131 patent is an act of infringement by Defendants of one or more claims of the ’131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

56. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’131 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

57. Upon information and belief, Defendants' offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the '131 patent under 35 U.S.C. § 271.

58. Defendants' infringement of the '131 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '131 patent.

59. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the '131 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '131 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

THIRD COUNT
(Defendants' Infringement of the '600 Patent)

60. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

61. Upon information and belief, Defendants included a paragraph IV certification to the '600 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the '600 patent.

62. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the '600 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the '600 patent is an act of infringement by Defendants of one or

more claims of the ’600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

63. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’600 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

64. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’600 patent under 35 U.S.C. § 271.

65. Defendants’ infringement of the ’600 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’600 patent.

66. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’600 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the ’600 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

FOURTH COUNT
(Defendants’ Infringement of the ’930 Patent)

67. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

68. Upon information and belief, Defendants included a paragraph IV certification to the ’930 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the ’930 patent.

69. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the ’930 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the ’930 patent is an act of infringement by Defendants of one or more claims of the ’930 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

70. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’930 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

71. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’930 patent under 35 U.S.C. § 271.

72. Defendants’ infringement of the ’930 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’930 patent.

73. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’930 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the '930 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

FIFTH COUNT
(Defendants' Infringement of the '791 Patent)

74. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

75. Upon information and belief, Defendants included a paragraph IV certification to the '791 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the '791 patent.

76. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the '791 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the '791 patent is an act of infringement by Defendants of one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

77. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the '791 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

78. Upon information and belief, Defendants' offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the '791 patent under 35 U.S.C. § 271.

79. Defendants' infringement of the '791 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '791 patent.

80. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the '791 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '791 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SIXTH COUNT
(Defendants' Infringement of the '975 Patent)

81. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

82. Upon information and belief, Defendants included a paragraph IV certification to the '975 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the '975 patent.

83. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the '975 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the '975 patent is an act of infringement by Defendants of one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq*., including under 35 U.S.C. § 271(e)(2)(A).

84. Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the '975 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

85. Upon information and belief, Defendants' offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the '975 patent under 35 U.S.C. § 271.

86. Defendants' infringement of the '975 patent has caused and will cause Supernus to suffer irreparable harm. Defendants' infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the '975 patent.

87. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the '975 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the '975 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

SEVENTH COUNT
(Defendants' Infringement of the '525 Patent)

88. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

89. Upon information and belief, Defendants included a paragraph IV certification to the '525 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the '525 patent.

90. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the '525 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the '525 patent is an act of infringement by Defendants of one or

more claims of the ’525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

91. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’525 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

92. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’525 patent under 35 U.S.C. § 271.

93. Defendants’ infringement of the ’525 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’525 patent.

94. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’525 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the ’525 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

EIGHTH COUNT
(Defendants’ Infringement of the ’278 Patent)

95. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

96. Upon information and belief, Defendants included a paragraph IV certification to the ’278 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the ’278 patent.

97. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the ’278 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the ’278 patent is an act of infringement by Defendants of one or more claims of the ’278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

98. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’278 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

99. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’278 patent under 35 U.S.C. § 271.

100. Defendants’ infringement of the ’278 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court. Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’278 patent.

101. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’278 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that

they would not be liable for infringement of the ’278 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

NINTH COUNT
(Defendants’ Infringement of the ’042 Patent)

102. Plaintiff repeats and re-alleges each of the foregoing Paragraphs as if fully set forth herein.

103. Upon information and belief, Defendants included a paragraph IV certification to the ’042 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of the Apotex Product before the expiration of the ’042 patent.

104. The submission and filing of ANDA No. 213369 with a paragraph IV certification to the ’042 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product before the expiration of the ’042 patent is an act of infringement by Defendants of one or more claims of the ’042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(e)(2)(A).

105. Defendants’ commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product that is the subject of ANDA No. 213369 will infringe, directly or indirectly, one or more claims of the ’042 patent under 35 U.S.C. § 271 *et seq.*, including under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

106. Upon information and belief, Defendants’ offering for sale and/or sale of the Apotex Product will induce and/or contribute to third-party infringement of one or more claims of the ’042 patent under 35 U.S.C. § 271.

107. Defendants’ infringement of the ’042 patent has caused and will cause Supernus to suffer irreparable harm. Defendants’ infringement will continue unless enjoined by the Court.

Supernus has no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit Defendants from infringing the ’042 patent.

108. As of the date of the May 13 Notice Letter, Defendants were aware of the existence of the ’042 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that they would not be liable for infringement of the ’042 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

i. A Judgment declaring that the ’898 patent is valid and enforceable;

ii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’898 patent by Defendants;

iii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’898 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

iv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’898 patent expires, including any regulatory extensions;

v. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’898 patent, including any regulatory extensions;

vi. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’898 patent;

vii. A Judgment declaring that infringement of the ’898 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’898 patent;

viii. A Judgment declaring that the ’131 patent is valid and enforceable;

ix. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’131 patent by Defendants;

x. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the

expiration of the ’131 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xi. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’131 patent expires, including any regulatory extensions;

xii. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’131 patent, including any regulatory extensions;

xiii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’131 patent;

xiv. A Judgment declaring that infringement of the ’131 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’131 patent;

xv. A Judgment declaring that the ’600 patent is valid and enforceable;

xvi. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into

the United States of the Apotex Product was an act of infringement of the ’600 patent by Defendants;

xvii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’600 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xviii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’600 patent expires, including any regulatory extensions;

xix. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’600 patent, including any regulatory extensions;

xx. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’600 patent;

xxi. A Judgment declaring that infringement of the ’600 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’600 patent;

xxii. A Judgment declaring that the ’930 patent is valid and enforceable;

xxiii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’930 patent by Defendants;

xxiv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’930 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxv. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’930 patent expires, including any regulatory extensions;

xxvi. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’930 patent, including any regulatory extensions;

xxvii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell,

and/or import any product that is the subject of ANDA No. 213369 that infringes the ’930 patent;

xxviii. A Judgment declaring that infringement of the ’930 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’930 patent;

xxix. A Judgment declaring that the ’791 patent is valid and enforceable;

xxx. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’791 patent by Defendants;

xxxi. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’791 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxxii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’791 patent expires, including any regulatory extensions;

xxxiii. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or

importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the '791 patent, including any regulatory extensions;

xxxiv. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the '791 patent;

xxxv. A Judgment declaring that infringement of the '791 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the '791 patent;

xxxvi. A Judgment declaring that the '975 patent is valid and enforceable;

xxxvii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the '975 patent by Defendants;

xxxviii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the '975 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xxxix. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the '975 patent expires, including any regulatory extensions;

xl. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’975 patent, including any regulatory extensions;

xli. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’975 patent;

xlii. A Judgment declaring that infringement of the ’975 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’975 patent;

xliii. A Judgment declaring that the ’525 patent is valid and enforceable;

xliv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’525 patent by Defendants;

xlv. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the

expiration of the ’525 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

xlvi. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’525 patent expires, including any regulatory extensions;

xlvii. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’525 patent, including any regulatory extensions;

xlviii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’525 patent;

xlix. A Judgment declaring that infringement of the ’525 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’525 patent;

l. A Judgment declaring that the ’278 patent is valid and enforceable;

li. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into

the United States of the Apotex Product was an act of infringement of the ’278 patent by Defendants;

lii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’278 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

liii. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’278 patent expires, including any regulatory extensions;

liv. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’278 patent, including any regulatory extensions;

lv. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’278 patent;

lvi. A Judgment declaring that infringement of the ’278 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’278 patent;

lvii. A Judgment declaring that the ’042 patent is valid and enforceable;

lviii. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 213369 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product was an act of infringement of the ’042 patent by Defendants;

lix. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation into the United States of the Apotex Product prior to the expiration of the ’042 patent, including any regulatory extensions, will constitute an act of infringement by Defendants;

lx. An Order that, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, the effective date of any approval of the Apotex Product shall be no earlier than the date on which the ’042 patent expires, including any regulatory extensions;

lxi. A Judgment pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees, and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 213369 until the expiration of the ’042 patent, including any regulatory extensions;

lxii. A Judgment awarding Supernus damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell,

and/or import any product that is the subject of ANDA No. 213369 that infringes the ’042 patent;

lxiii. A Judgment declaring that infringement of the ’042 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of ANDA No. 213369 that infringes the ’042 patent;

lxiv. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Supernus its attorneys’ fees and costs; and

lxv. Such other and further relief as this Court may deem just and proper.

Dated: June 26, 2020

Respectfully submitted,

By: s/ William C. Baton

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: June 26, 2020

Respectfully submitted,

By: s/ William C. Baton

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